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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,102	09/10/2003	Mitchell J. Bellucci	302490.3000-100	6872

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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,102	BELLUCCI ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 10 September 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/20/05, 2/2/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 10 is objected to because of the following informalities:

at line 2, the limitations "having a cavity in which an umbilical cord is positioned" should apparently read --having a cavity adapted to receive an umbilical cord-- to avoid a positive recitation of a body part.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 11-12 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Aceti et al. (US Patent No. 6,540,675).

In regards to claim 1, Aceti et al. disclose(s) an umbilical cord sampling device comprising at least one sampling needle 53 operatively connected to a removable cassette containing a sampling reservoir 50 (see fig. 1; column 2/lines 26-38; column 3/lines 5-10; column 12/lines 30-36).

In regards to claim 11, Aceti et al. disclose(s) an umbilical cord sampling device further comprising a plurality of sampling needles 53 (see column 2/lines 26-38).

In regards to claim 12, Aceti et al. disclose(s) an umbilical cord sampling device further comprising a sensor (see column 9/lines 62-64; column 10/lines 9-16, 42-45 & 56-59).

In regards to claim 14, Aceti et al. disclose(s) an umbilical cord sampling device further comprising a meter (see column 11/lines 26-37 & 56-60).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aceti et al. ('675) in view of Knippscheer et al. (US Patent No. 5,114,672).

Aceti et al. disclose a system, as described above, that teaches all the limitations of the claims except Aceti et al. do not teach a roller. However, Knippscheer et al. disclose a system comprising a roller 70 (see fig. 4). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Aceti et al. with a roller similar to that of Knippscheer et al. in order to mix the blood inside the umbilical cord with an anticoagulant (see Knippscheer et al., column 4/lines 4-9, 43-49 & 52-57).

6. Claims 4-5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aceti et al. ('675) in view of Lauks et al. (US Patent No. 5,779,650).

In regards to claim 4, Aceti et al. disclose(s) an umbilical cord sampling device further comprising a system including a removable cassette column 3/lines 5-10; column 12/lines 30-36).

In regards to claim 5, Aceti et al. disclose(s) an umbilical cord sampling system further comprising an analyzer (see column 11/lines 26-37 & 56-60).

In regards to claim 9, Aceti et al. disclose(s) an umbilical cord sampling system wherein the analyzer is in operative communication with a computer (see column 11/lines 26-37 & 56-60).

Aceti e et al. disclose a system, as described above, that teaches all the limitations of the claim except Aceti et al. do not disclose a docking unit. However, Lauks et al. disclose a system comprising a docking unit 120 that mates with a removable cassette 24 (see fig. 1; column 5/lines 53-64). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Aceti et al. with a docking unit similar to that of Lauks et al. in order to stably secure the reservoir chamber to the device (see Lauks et al., column 6/lines 4-6).

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aceti et al. ('675) in view of Lauks et al. ('650) further in view of Lauks et al. (US Patent No. 5,096,669).

Aceti et al. as modified by Lauks et al. ('650) disclose a system, as described above, that teaches all the limitations of the claim except Aceti et al. as modified by Lauks et al. ('650) do not teach a printer. However, Lauks et al. ('669) disclose a system

comprising a printer (see fig. 1; column 4/lines 21-25). Since Aceti et al. as modified by Lauks et al. ('650) disclose a system comprising a visual display (see Aceti et al., column 11/lines 56-60), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Aceti et al. as modified by Lauks et al. ('650) with a printer similar to that of Lauks et al. ('669) since both will serve the same purpose of outputting the results of the analysis as is well known in the art.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aceti et al. ('675) in view of Lauks et al. ('650) further in view of Baker et al. (US Patent No. 4,654,127).

Aceti et al. as modified by Lauks et al. ('650) disclose a system, as described above, that teaches all the limitations of the claim except Aceti et al. as modified by Lauks et al. ('650) do not teach a printer. However, Baker et al. disclose a system comprising a printer (see column 4/lines 60-68). Since Aceti et al. as modified by Lauks et al. ('650) disclose a system comprising a visual display (see Aceti et al., column 11/lines 56-60), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Aceti et al. as modified by Lauks et al. ('650) with a printer similar to that of Baker et al. since both will serve the same purpose of outputting the results of the analysis as is well known in the art (see Baker et al., see column 4/lines 60-68).

9. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aceti et al. ('675) in view of Lauks et al. ('650) further in view of Gauthier et al. (US Patent No. 6,017,318).

In regards to claim 7, Aceti et al. as modified by Lauks et al. disclose a system, as described above, that teaches all the limitations of the claim except Aceti et al. as modified by Lauks et al. do not teach a bar code reader. However, Gauthier et al. disclose a system comprising a bar code reader (see column 24/lines 5-6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Aceti et al. as modified by Lauks et al. with a bar code reader similar to that of Gauthier et al. in order to read the information indicative of the specific activity of the tests (see column 12/lines 39-42 & 45-49).

Moreover, in regard to claim 8, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Aceti et al. as modified by Lauks et al. and Gauthier et al. with a magnetic card reader since such a modification would amount to a design choice. It has previously been held that changing aesthetic design (i.e. swapping a bar code reader with a magnetic card reader) is not patentable--See In re Seid, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

10. Claims 3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aceti et al. ('675) in view of Gruenberg (US Patent No. 5,690,646).

Aceti et al. disclose a system, as described above, that teaches all the limitations of the claims except Aceti et al. do not teach a base. However, Gruenberg discloses a

system comprising a base 12 (see figs. 1-3). It would have been obvious to one of ordinary skill in the art at the time Applicant' s invention was made to provide a system similar to that of Aceti et al. with a base system similar to that of Gruenberg in order to securely strap the sample (see Gruenberg, column 1/lines 26-40).

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aceti et al. ('675) in view of Hessel et al. (US Patent No. 5,520,699).

Aceti et al. disclose a system, as described above, that teaches all the limitations of the claims except Aceti et al. do not explicitly teach a pH sensor. However, Hessel et al. discloses a system comprising a pH sensor (see column 10/lines 59-66). Since Aceti et al. teach a sensor, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Aceti et al. with a pH sensor since such a modification would amount to a design choice. It has previously been held that changing aesthetic design (i.e. swapping a glucose sensor with a pH sensor) is not patentable--See In re Seid, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

12. Claims 15-16 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruenberg (US Patent No. 5,690,646) in view of Hessel et al. (US Patent No. 5,520,699).

Gruenberg disclose(s) a method, comprising the steps of:

providing an umbilical cord sampling device 10 having at least one sampling needle 28 operatively connected to at least one sampling reservoir (i.e. blood collection bag);

placing an umbilical cord segment in the umbilical cord sampling device 10 (see figs. 1-2);

penetrating a fluid-containing lumen of the umbilical cord segment with a sampling needle 28 (see fig. 3);

collecting the fluid in a sampling reservoir.

Gruenberg discloses a method, as described above, that teaches all the limitations of the claim except Gruenberg does not teach a step of analyzing the collected fluid to determine values of physiological parameters. However, Hessel et al. disclose a method comprising the step of analyzing a collected fluid with a probe to determine values of physiological parameters; wherein the method comprising measuring fluid with a sensor (probe); wherein the method comprises measuring blood gas value (i.e. saturated oxygen measurements); wherein the method comprises measuring blood pH (see column 10/lines 56-66). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a sensor similar to that of Hessel et al. in order to make measurement of the blood (see Hessel et al., column 10/lines 59-60).

13. Claims 17 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruenberg ('646) in view of Hessel et al. ('699) further in view of Aceti et al. (US Patent No. 6,540,675).

Gruenberg as modified by Hessel et al. discloses a method, as described above, that teaches all the limitations of the claims except Gruenberg as modified by Hessel et al. does not disclose measuring a blood analyte or communicating values to a

computer. However, Aceti et al. discloses a method comprising the steps of disclose measuring a blood analyte (i.e. glucose) and communicating values to a computer (see column 3/lines 13-14 & 21-25; column 9/lines 62-64; column 10/lines 9-16, 42-45 & 56-59; column 11/lines 26-37 & 56-60).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Gruenberg as modified by Hessel et al. with a step of measuring a blood analyte similar to that of Aceti et al. in order to monitor the blood analyte level (i.e. whether or not is falls within the norm).

Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Gruenberg as modified by Hessel et al. with a step of communicating the values to a computer similar to that of Aceti et al. in order to report the measured value (see Aceti et al., column 11/lines 15-25).

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 7,025,774 to Freeman et al. discloses a tissue penetration device.

US Patent No. 6,155,991 to Beat et al. discloses an apparatus and method for collecting blood samples.

US Patent No. 5,053,025 to Knippscheer discloses a method and apparatus for extracting fluid.

US Patent No. 5,575,795 to Anderson discloses an umbilical cord holder.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RTT

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